

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N-0076]

DDM  
Display Date 2-27-04  
Publication Date 3-1-04  
Certifier R. LEDESMA

per  
V. Greenwald,  
OFR 2-26-04  
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**Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Reopening of the Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advanced notice of proposed rulemaking, reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 45 days the comment period for an advanced notice of proposed rule making (ANPRM) published in the **Federal Register** of July 11, 2003 (68 FR 41507), in which FDA is requesting information and data that potentially could be used to establish new nutrient content claims about trans fatty acids (trans fat); to establish qualifying criteria for trans fat in current nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. Since publication of the ANPRM on July 11, 2003, the Institute of Medicine of the National Academy of Science (IOM/NAS) issued a report entitled "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification." FDA is reopening the comment period to receive comments that consider the information in the IOM/NAS report specific to this

ANPRM and trans fat labeling. Information and data obtained from comments to this ANPRM may be used to help draft a proposed rule on trans fat.

**DATES:** Submit written or electronic comments by [*insert date 45 days after date of publication in the **Federal Register***].

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *<http://www.fda.gov/dockets/ecomments>*.

**FOR FURTHER INFORMATION CONTACT:** Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1450, FAX 301-436-2636.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA issued an ANPRM to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids (trans fat); to establish qualifying criteria for trans fat in current nutrient content claims for saturated fatty acids (saturated fat) and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. We (FDA) also requested comments on whether we should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the nutrition facts panel or as a disclosure statement in conjunction with claims to enhance consumers understanding about such cholesterol-raising lipids and how to use

the information to make healthy food choices. The comment period was open until October 9, 2003.

Since the end of the previous comment period, the IOM/NAS issued a report entitled “Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification” (the 2003 report) in which the overarching goal is to have updated nutrition labeling that consumers can use to make informed dietary choices (Ref. 1). In response to requests received in this docket, we are reopening the comment period to allow interested persons the opportunity to consider the 2003 report and its discussion specific to trans fat labeling in comments submitted on the ANPRM. The IOM/NAS’s dietary reference intake (DRI) 2002 report on macronutrients (Ref. 2) did not establish an estimated average requirement (EAR), an adequate intake (AI), or an acceptable macronutrient distribution range (AMDR) for trans fat because the presence in the diet meets no known nutritional need, hence there are no DRI values that can be readily used as the basis for a trans fat daily value (DV). Therefore, to establish a DV for trans fat, the 2003 report suggests the use of food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-promoting diets for diverse populations. It specifically suggests estimating minimal trans fat intake levels via menu modeling and then further evaluating them against achievable health-promoting diets (identified in dietary survey data) in order to arrive at appropriate recommendations for the intake of trans fat. We are requesting comment on the approach recommended in the 2003 report to estimate minimum trans fat intakes within a nutritionally adequate North American diet and use this value to establish a DV for trans fat.

The 2003 report also recommends that saturated fat and trans fat amounts be listed on separate lines, but that one numerical value for the percent DV be included in the nutrition facts panel for these two nutrients together. The 2003 report recognizes that trans fat and saturated fat are chemically distinct and acknowledges that research demonstrates different physiological effects among the fatty acids; however, both trans fat and saturated fat raise total and low density lipoprotein (LDL) cholesterol levels, which are potential contributors to coronary heart disease risk. We are requesting comment about the development of a joint DV for saturated and trans fats. If a joint DV for saturated and trans fats is pursued, we are requesting comment about the use of the same approach that the 2003 report recommended for establishing a DV for trans fat (noted previously) to establish a new DV for saturated fat that would then be added to the DV for trans fat to establish a new combined DV, or, alternatively, to directly establish a joint DV for saturated and trans fats. Additionally, we are requesting comment about how either a DV for trans fat or a joint DV for saturated and trans fats may affect the qualifying criteria for trans fat in trans fat nutrient content claims and qualifying criteria for saturated and trans fats in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids as well as disclosure and disqualifying criteria for saturated and trans fats to help consumers make healthy food choices.

We are also requesting comment on whether a DV for trans fat or joint DV for saturated and trans fats would eliminate the necessity for considering a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, trans fat, or cholesterol in a food or in the

diet or a message about the role of such cholesterol-raising lipids in increasing the risk of CHD. Further, we are requesting comment on whether a DV for trans fat or a joint DV for saturated and trans fats would eliminate the need for a footnote about trans fat, either alone or in combination with saturated fat and cholesterol.

Information and data obtained from comments and from consumer studies may be used to help draft a proposed rule on trans fat to do the following: (1) Establish criteria for certain nutrient content or health claims; (2) require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the nutrition facts panel; and (3) develop a DV for trans fat either alone or in combination with saturated fat for use with a joint percent DV for saturated and trans fat in the nutrition facts panel to assist consumers in maintaining healthy dietary practices. At a later date, we will solicit comment on the remaining parts of the 2003 report.

## **II. How to Submit Comments**

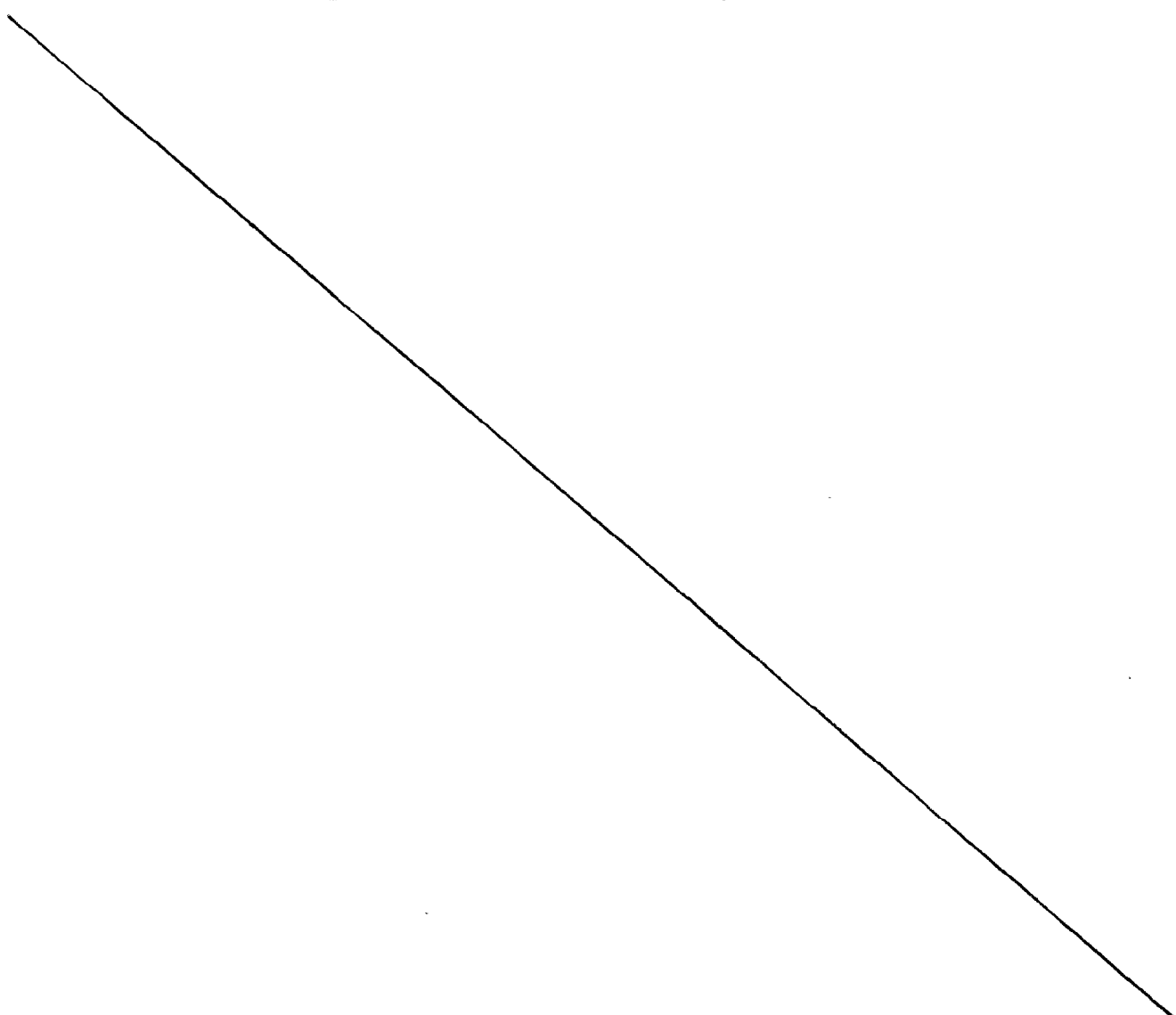
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this ANPRM. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## **III. Electronic Access**

Persons with access to the Internet may obtain the ANPRM text or PDF at <http://www.gpoaccess.gov/fr/index.html> by browsing the "Table of Contents from Back Issues" and select the publication date of Friday, July 11, 2003.

#### IV. References

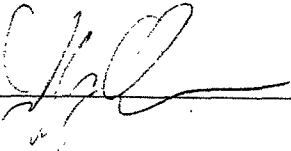
The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. IOM/NAS 2003, "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification," National Academy Press, Washington DC (Internet address: <http://www.iom.edu/report.asp?id=17117>).
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2. IOM/NAS 2002, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids," National Academy Press, Washington, DC (Internet address: <http://www.iom.edu/report.asp?id=4340>).

Dated: 7/20/04

February 20, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.  
[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

